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PC10734A

# REMARKS

## 35 U.S.C. § 103(a)

Claims 6-7, 10, 14-17 and 30 have been rejected as allegedly being unpatentable over WO 97/24369 and U.S. Patent No. 6,107,306 in view of Hahn.

Applicants respectfully submit that the presently claimed invention is patentable over WO 97/24369 and U.S. Patent No. 6,107,306 in view of Hahn because the combination of WO97/24369 and U.S. Patent No. 6,107,306 in view of Hahn does not teach or suggest to one skilled in the art that a growth hormone secretagogue can be used to treat systemic lupus erythematosus (SLE) in a patient having SLE.

In determining whether a claimed invention is obvious or not, the Supreme Court set forth the factual inquiries to be considered in *Graham v. John Deere*, 383 U.S. 1, 148 (1966). The inquiries include:

1. determining the scope and content of the prior art;
2. ascertaining the differences between the prior art and the claims at issue;
3. resolving the level of ordinary skill in the pertinent art; and
4. evaluating evidence of secondary considerations.

Additionally, in determining obviousness or not, the claimed invention must be considered as a whole; the references must be considered as a whole and must suggest the desirability of making the combination; the references must be viewed without the benefit of impermissible hindsight; and a reasonable expectation of success is the standard with which obviousness is determined. MPEP, Eighth Edition, Revision No. 2, Section 2141, Subsection titled "Basic Considerations which apply to Obviousness Rejections."

Using the well know criteria set forth above, Applicants respectfully submit that the present invention, when considered as a whole, is not obvious over the combination of WO 97/24369 and U.S. Patent No. 6,107,306 in view of Hahn. The presently claimed invention relates to the use of a growth hormone secretagogue to treat SLE. Growth

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hormone secretagogues are compounds that increase the secretion of growth hormone from the pituitary gland. It is admitted in the Office Action that none of the cited references teach that growth hormone secretagogues can be used to treat SLE. In fact, nowhere in WO 97/24369 and U.S. Patent No. 6,107,306 is SLE mentioned.

Hahn is a section from a medical text that describes SLE, which is a very complicated disease that has many clinical manifestations. A large number of clinical manifestations of SLE are listed on Table 284-2 of Hahn. Hahn nowhere suggests that SLE can be treated using a growth hormone secretagogue. In fact, growth hormone secretagogues are not even mentioned in Hahn. Thus, the references, when considered as a whole, can not suggest the desirability of making the combination.

In the rejection, it is alleged that "one of ordinary skill in the art would have been motivated to employ the elected compound to treat SLE because the elected compound is useful to treat the clinical manifestations of SLE such as peripheral neuropathy and renal involvement." Applicants assert that this reasoning does not consider the claimed invention as a whole, but instead only certain manifestations have been selected to make the rejection. This reasoning is akin to saying that AIDS can be treated with an antifungal compound because one clinical manifestation of a person with AIDS is a fungal infection. One skilled in the art would not consider the use of an antifungal compound as being able to treat AIDS. Similarly, one skilled in the art would not consider a compound which can be used to treat peripheral neuropathy and renal involvement to be able to treat SLE.

The Examiner states in responding to the Remarks made in the prior response dated December 22, 2003, that "in other words, the patient populations recited in the claims include those who have SLE symptoms such as peripheral neuropathy and renal involvement. Therefore, the herein elected compound would be reasonably expected to be useful in treating SLE patients with peripheral neuropathy and renal involvement." No scientific basis was cited for this assertion. SLE is a disease of unknown cause in which tissues and cells are damaged by pathogenic autoantibodies and immune complexes (See Hahn, first paragraph). It does not follow that the peripheral neuropathy

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and renal involvement in SLE patients could be treated because it would not have been clear to one skilled in the art if the biological cause of these symptoms are the same as other peripheral neuropathies and renal involvements. Consequently, there is no motivation to combine the references. In other words, the references do not expressly provide the motivation to make the combination and the knowledge generally available at the time the invention was made did not provide suitable motivation to treat SLE using a growth hormone secretagogue due to the uncertain biological mechanism. This uncertainly does not provide for the requisite reasonable expectation of success in treating SLE using a growth hormone secretagogue.

Last, because it would not have been obvious to one skilled in the art to use a growth hormone secretagogue to treat SLE, it could not have been obvious to use a combination of a growth hormone secretagogue and another therapeutically active compounds useful in treating SLE.

In view of the remarks made above, applicants believe that claims 6-7, 10, 14-17 and 30 are in condition for allowance. Applicants also respectfully request that claims 8, 9 and 11-13 be rejoined into the claims being considered, because if generic claim 1 is allowable, Applicants believe that the species claims 8, 9 and 11-13 would also be allowable. To rejoin the claims would be greatly appreciated to avoid the expense of filing divisional applications. Reconsideration and allowance of claims 6-7, 10, 14-17 and 30 as well as rejoinder and allowance of claims 8, 9, 11-13 is respectfully requested.

Applicants have been required to elect a single species for prosecution. Applicants hereby elect the species of claim 9, which is 2-amino-N-(2-(3a-(R)-benzyl-2-methyl-3-oxo-2,3,3a,4,6,7-hexahydro-pyrazolo-[4,3-c]pyridin-5yl)-1-(R)-benzyloxymethyl-2-oxo-ethyl)-isobutyramide. The claims that read on the elected species are claims 1-10 and 15-16.

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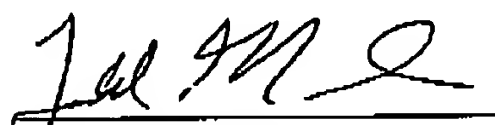
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Applicants believe that the claims pending in this Application are in condition for allowance. The allowance of claims 1-10 and 15-16 is respectfully requested.

Respectfully submitted,

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